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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,489	01/23/2001	Lisa Joanne Drewe	41577/252464	5644

23370 7590 05/05/2006

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,489	DREWE ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,6,8-12 and 18-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6,8-12 and 18-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/15/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action filed on February 23, 2006 has been entered.

Status of the Application

2. Claims 1-2, 5-6, 8-12, 18-26 are pending. Claims 3-4, 7, 13-17 are cancelled. New claims 25-26 are added. All amendments and arguments have been thoroughly reviewed and deemed persuasive for the reasons that follow. This action is made Non-Final.

New Grounds of Rejections

Objection to Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract recites the legal phraseology "said", which should be avoided.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Graham et al. (WO 97/05280).

Graham et al. teach a kit for detecting a target nucleic acid in a sample, wherein the kit comprises a peptide nucleic probe sequence which is immobilized on a waveguide of an evanescent wave detector apparatus (see page 57, line 6-35, page 58, line 1-22, page 14, line 13-16, page 47, line 1-3, page 49, line 13-35, page 50, line 1-12), and a set of primers (see page 58, line 9-16 indicates a kit comprises other reagents for manipulating target nucleic acids, page 62, line 21-25, page 82, line 18-35, page 83, line 1-35, page 84, 1-12 indicating that the kit comprising other reagents include primers).

With regard to claim 26, Graham et al. teach that the kit evanescent wave detector apparatus, that is a surface plasmon resonance detector (see page 14, line 13-16, page 47, line 1-3, page 49, line 13-35, page 50, line 1-12). Accordingly the disclosure of Graham et al. anticipates the instant claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 1, 2, 5-6, 8-9, 12, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vary et al. (USPN. 5,800,984) in view of Egholm et al. (WO 96/02558 A1).

Vary et al. teach a method of claims 1, 6, for detecting the presence or absence of a target nucleic acid sequence in a sample comprising

(a) amplifying said target nucleic acid and introducing a purine rich region into the target sequence during amplification, wherein the resulting target is able to bind to a complementary triplex forming probe (see col. 5, line 43-55, col. 6, line 45-67, col. 8, line 7-49, col. 9, line 45-54, indicating purine rich region is introduced into PCR product during amplification reaction, wherein it is capable of hybridizing with a complementary triplex forming probe);

(b) detecting the presence of triplex structures resulting from the hybridization of target sequence with the probe, wherein the detection of the presence of the triples structures indicates the presence of the target nucleic acid sequence in the sample (see col. 58-64, col. 8, line 50-56, col. 9, line 54-63).

With regard to claim 5, 22, Vary et al. teach that the amplification reaction is a polymerase chain reaction (see col. 5, line 43-58, col. 8, line 7-10);

With regard to claim 8, Vary teach that the PCR primers comprise plurality of pyrimidines at the 5' end (see col. 6, line 60 indicating the triplex primer comprising plurality of pyrimidines);

With regard to claim 9, 23, Vary et al. teach that the probe is immobilized to a solid support (see col. 5, line 63-67, col. 6, line 1-14);

With regard to claim 12, 24, Vary et al. teach the triplex structure is detected by a gel retardation method (see col. 9, line 54-67).

However, Vary did not specifically teach use of a peptide nucleic acid probe to form triplex structure.

Egholm et al. teach use of a peptide nucleic acid for diagnostic purposes, including identification of certain sites in double stranded DNA and for use in triplex forming motif (see page 6, line 19-30). Egholm et al. teach that said peptide nucleic acid is a bis-PNA (see page 6, line 19-22). Egholm et al. also teach that the PNAs provide high thermal stability, greater affinity and stable hybridization with DNA and RNA targets and resistant to degradation by enzymes (see page 3, line 15-35, page 4, line 24-29) and provide improved affinity to purine-rich regions (see page 4, line 1-36, page 17, line 13-37, page 18, line 1-26).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for detecting the presence of a target nucleic acid in a sample as disclosed by Vary et al. et al. with a step of using a PNA probe for detecting said target nucleic acid as taught by Egholm et al. for the purpose of developing an improved detection method for enhancing the stability and specificity of the hybridization complex. One skilled in the art would be motivated to combine the method as disclosed by Vary et al. in a manner taught by Egholm et al. by the inclusion of a step of using PNA probe because Egholm et al. explicitly taught that the PNAs provide high thermal stability, greater affinity and stable hybridization with DNA and RNA targets and resistant to degradation by enzymes (see page 3,

line 15-35, page 4, line 24-29) and provide improved affinity to purine-rich regions (see page 4, line 1-36, page 17, line 13-37, page 18, line 1-26). An ordinary artisan would have a reasonable expectation of success that inclusion of the step of PNA probe for detection of the target nucleic acid would result in improving the stability and specificity of the hybridization complexes with purine-rich targets as suggested by Egholm et al. and such modification of the method would be obvious over the cited prior art in the absence of secondary considerations.

B. Claims 10-11, 18-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Vary et al. (USPN. 5,800,984) in view of Egholm et al. (WO 96/02558 A1) as applied to claims 1, 2, 5-6, 8-9, 12, 22-24 above, and further in view of Graham et al. (WO 97/05280).

Vary et al. in view of Egholm et al. teach a method for detecting the presence of a target nucleic acid in a sample as discussed above in section 5A.

However, neither Vary et al. nor Egholm et al. teach the use of a waveguide detector that is a surface plasmon resonance detector for detecting the presence of said target nucleic acid.

Graham et al. teach a method for detecting the presence of a target nucleic acid wherein Graham et al. teach a method comprises surface enhanced Raman scattering techniques for detecting target nucleic acids (see page 10, line 1-34). Graham et al. teach that the method comprises hybridizing target with SERS- active surface, which is in the form of a coating on a waveguide (see page 23, line 8-32).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for detecting the presence of a target nucleic acid in a sample as disclosed by Vary et al. et al. in view of Egholm et al. with a step of using waveguide detector as taught by Graham et al. for the purpose of developing a sensitive detection

method for the purpose of detecting the target nucleic acid. One skilled in the art would be motivated to combine the method as disclosed by Vary et al. in view of Egholm et al. in a manner taught by Graham et al. by the inclusion of a step of using a waveguide detector because Graham et al. explicitly taught that the use of the waveguide detector provides an increased sensitivity in detecting low copy number target nucleic acid s in a sample and potentially be a quick and cost-effective method for detecting target nucleic acids in a sample, wherein the combined effect of surface enhancement and the resonance effect result in increases in sensitivity and robustness (see page 4, line 35, page 5, line 1-14, page 11, line 5-34). An ordinary artisan would have a reasonable expectation of success that inclusion of the waveguide detector for detection of the target nucleic acid would result in improving the sensitivity, robustness and cost-effective method for detecting the target nucleic acids as suggested by Graham et al. and such modification of the method would be obvious over the cited prior art in the absence of secondary considerations.

Response to arguments:

6. With regard to the rejection of claims 1, 5-6, 8-12, 14, 16, and 18-24 under 35 USC 103(a) as being unpatentable over Vary et al. in view of Kai et al., Applicants arguments are fully considered and found persuasive. The rejection is withdrawn in view of new grounds of rejection.

7. With regard to the rejection of claim 2 under 35 USC 103(a) as being unpatentable over Vary et al. in view of Kai et al. further in view of Armitage et al., Applicants arguments are fully considered and found persuasive. The rejection is withdrawn in view of new grounds of rejection.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Patent xaminer
Art Unit 1637

Prabha Chunduru
SURYAPRABHA CHUNDURU 4/28/06
PATENT EXAMINER